

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-0842V

ALEXEI RODIONOV,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: October 18, 2023

Bridget Candace McCullough, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Jennifer Leigh Reynaud, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On July 10, 2020, Alexei Rodionov filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.² (the “Vaccine Act”), amending it three years later. Petitioner alleges that he suffered a shoulder injury related to vaccine administration (“SIRVA”) resulting from influenza (“flu”) and tetanus diphtheria acellular pertussis (“Tdap”) vaccines received on October 19, 2017. Amended Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters.

¹ Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

For the reasons discussed below, I find that a preponderance of the evidence supports a finding that the residual effects of Petitioner's condition continued for more than six months, and that Petitioner has satisfied the remaining requirements for entitlement.

I. Relevant Procedural History

A year after the claim's activation and the filing of relevant medical records, the parties attempted settlement but were unsuccessful. Accordingly, on October 18, 2022, Petitioner filed a motion for a ruling on the record, along with a supplemental affidavit (ECF Nos. 40, 41). Respondent offered his own brief on December 15, 2022 (ECF No. 42). The matter of Petitioner's entitlement to compensation is now ripe for resolution.

II. Factual Findings and Ruling on Entitlement

A. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v.*

Sec'y of Health & Human Servs., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). The Federal Circuit has “reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient’s physical conditions.” *Kirby v. Sec'y of Health & Human Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021) (explaining that a patient may not report every ailment, or a physician may enter information incorrectly or not record everything he or she observes).

In addition to requirements concerning the vaccination received and the lack of other award or settlement,³ a petitioner must establish that he or she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination he or she received. Section 11(c)(1)(C). The Vaccine Act further includes a “severity requirement,” pursuant to which a petitioner demonstrate that they:

- (i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

Section 11(c)(1)(D).

“[T]he fact that a Petitioner has been discharged from medical care does not necessarily indicate that there are no remaining or residual effects from her alleged injury.” *Morine v. Sec'y of Health & Human Servs.*, No. 17-1013, 2019 WL 978825, at *4 (Fed. Cl. Spec. Mstr. Jan. 23, 2019); see also *Herren v. Sec'y of Health & Human Servs.*, No. 13-1000V, 2014 WL 3889070, at *3 (Fed. Cl. Spec. Mstr. July 18, 2014) (“a discharge from medical care does not necessarily indicate there are no residual effects”). “A treatment gap . . . does not automatically mean severity cannot be established.” *Law v. Sec'y of Health & Human Servs.*, No. 21-0699V, 2023 WL 2641502, at *5 (Fed. Cl. Spec. Mstr. Feb. 23, 2023) (finding severity requirement met where Petitioner sought care for under three months and had met physical therapy goals but still lacked full range of motion and experienced difficulty with certain activities, then returned to care nearly five months later reporting stiffness and continuing restrictions in motion); see also *Peeples v. Sec'y of Health & Human Servs.*, No. 20-0634V, 2022 WL 2387749 (Fed. Cl. Spec. Mstr. May

³ In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception and has not filed a civil suit or collected an award or settlement for his or her injury. Section 11(c)(1)(A)(B)(E).

26, 2022) (finding severity requirement met where Petitioner sought care for four months, followed by fifteen month gap); *Silvestri v. Sec'y of Health & Human Servs.*, No. 19-1045V, 2021 WL 4205313 (Fed. Cl. Spec. Mstr. Aug. 16, 2021) (finding severity requirement satisfied where Petitioner did not seek additional treatment after the five month mark).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying Qualifications and Aids to Interpretation (“QAI”) are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

A special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

B. Relevant Factual History

Although I have reviewed the entire record, this ruling contains only an overview of facts relating to the severity requirement and Petitioner’s entitlement to compensation.

1. Medical Records

On October 19, 2017, during a primary care appointment, Petitioner received flu and Tdap vaccines in his left deltoid. Ex. 1 at 2. Twelve days later, he returned to the relevant treater, Dr. Thao Tran, reporting that since he got the vaccines his left shoulder had been “really sore.” Ex. 2 at 31. He had been self-treating with ice, naproxen, topical cream, and hot showers. *Id.* It was improving, but he was unable to sleep on that side. *Id.* On examination, he had full range of motion (“ROM”), but his deltoid area was tender to palpation and slightly warm. *Id.* at 32. Dr. Tran determined it was likely myalgia from the vaccinations and prescribed methylprednisolone and amoxicillin and ordered shoulder x-rays. *Id.*

On December 28, 2017, Petitioner was treated by nurse practitioner (“NP”) Diana Ryan for pain in his nipple and left shoulder. Ex. 2 at 33. The record does not document any further evaluation or treatment of his shoulder. *Id.* at 33-34.

Seven months later, on August 3, 2018, Petitioner saw orthopedist Dr. Sue Lee complaining of left shoulder pain for the past nine months. Ex. 12 at 2. He complained of severe pain with all activities of daily living and limited ROM. *Id.* His pain improved with rest. *Id.* On examination, his active ROM was reduced in his left shoulder compared to his right shoulder. *Id.* He had positive impingement signs on the left side. *Id.* Dr. Lee found that Petitioner’s complaints and exam findings were most consistent with rotator cuff pathology, and recommended conservative treatment with physical therapy (“PT”). *Id.* at 3. Dr. Lee also administered a steroid injection. *Id.*

Later that same month, Petitioner underwent a PT evaluation. Ex. 5 at 106. He complained of left shoulder pain that started ten months earlier when he received flu and Tdap vaccines. *Id.* Initially the pain was so severe that he could not move his left arm. *Id.* He also reported that he had lost his insurance in December 2017, and was unable to get medical attention. *Id.* The pain started to subside in one to two months, but he continued to have limited active ROM in his left shoulder and pain with movement. *Id.* He also continued to have some difficulty sleeping and driving. *Id.* He was experiencing a pain level of four to eight (out of ten) at worst. *Id.* On examination, his left shoulder active ROM was reduced, while it was within normal limits in his other shoulder. *Id.* at 107.

Petitioner continued PT through January 21, 2019. Ex. 5 at 24. He also underwent a left shoulder MRI (Ex. 4 at 46) and followed up with Dr. Lee (Ex. 12 at 4) and NP Ryan (Ex. 2 at 4).

2. Affidavits

Petitioner filed two affidavits in support of his claim. Exs. 9, 13. Petitioner explained that he went to his PCP's office for the Tdap shot in anticipation of the birth of his son. Ex. 13 at ¶ 1. While there, he agreed to get the flu shot as well. *Id.* The nurse injected the vaccines high into his shoulder to avoid a tattoo on his left upper arm. *Id.* at ¶ 2. It hurt a little more than usual, and worsened as the day went on, to the point that he needed Tylenol by bedtime. *Id.* When he awoke the next morning, he was still in pain. *Id.*

His shoulder pain persisted and worsened, and was at a level ten within a few days. Ex. 13 at ¶ 3. He took over the counter pain relievers and used a topical cream, with no relief. *Id.* at ¶ 4. Initially, hot showers helped loosen his shoulder up a little, but it did not last and after a few days the heat did not help at all. *Id.* He could not sleep on his left side, and had difficulty falling asleep and staying asleep, waking several times during the night due to pain. *Id.*

Petitioner's son was born two days after he received the vaccines. Ex. 13 at ¶ 5. He was unable to lift or play with his son normally due to the pain and limited ROM. *Id.* He went to his PCP after a couple of weeks and was given a steroid, which helped reduce the pain a little and he regained some movement, although his ROM remained very

limited. *Id.* at ¶ 6. As the weeks and months went by, he gradually gained more ROM in his left shoulder, although it remained limited. *Id.* at ¶ 8.

Petitioner averred that his quality of life was “extremely affected” as there were everyday things he could not do or had trouble doing, and he his pain remained “pretty bad” for a long time. Ex. 13 at ¶ 10. For the first two to three months, his pain levels remained severe, between seven and ten. Up to 18-24 months after vaccination, his pain remained between three and six, sometimes worse especially with activity and PT. *Id.* He could not do a push up until about 30 months after vaccination. *Id.* at ¶ 11.

C. The Parties’ Arguments

Petitioner argues that he has established the QAI requirements for a Table SIRVA, and thus I should find that he is entitled to compensation. Petitioner’s Motion for a Ruling on the Record, filed Oct. 18, 2022 (ECF No. 41) (“Mot.”). Petitioner asserts that he had no prior history of any shoulder pain or injuries, the onset of his symptoms occurred within 48 hours of vaccine administration, his pain and reduced ROM were limited to the vaccinated shoulder, and there is no other condition or abnormality that would explain his left shoulder pain. Mot. at *6-8.

With respect to the statutory severity requirement, Petitioner argues that there is preponderant evidence that he suffered the residual effects of his SIRVA for more than six months. Mot. at *11. Petitioner acknowledges a gap in treatment due to losing his medical insurance, but asserts that, “[t]here is no evidence in the record, and in fact would be contrary to the evidence of record, for Respondent to suggest that Petitioner’s complaints and examination findings in August of 2018 and beyond were related to some other intervening event.” *Id.* at *10-11.

In response, Respondent acknowledges that Petitioner has met the Table and QAI requirements for SIRVA. Respondent’s Response, filed Dec. 15, 2022 (ECF No. 42) (“Resp.”). However, Respondent argues that “it is unclear from the current record whether petitioner has satisfied the Act’s severity requirement.” *Id.* at *4. Respondent notes that Petitioner was seen twice in the ten weeks following vaccination, with an apparent improvement in his shoulder pain, followed by an eight month gap in treatment. *Id.* at *4-5. Ultimately, Respondent “defers to the Court as to whether petitioner has provided preponderant proof that he has satisfied the criteria set forth in 42 U.S.C. § 300aa-11(c)(1)(D).” *Id.* at *5.

D. Factual Finding Regarding QAI Criteria for Table SIRVA

Respondent does not contest that Petitioner has met the SIRVA Table and QAI requirements, and they are also satisfied by a preponderance of the evidence. The onset of Petitioner's shoulder pain more likely than not occurred within 48 hours of vaccination. Ex. 2 at 31. Petitioner did not have either a history of pain, inflammation, or dysfunction of his left shoulder, or any other condition or abnormality, that would explain his condition after vaccination. Ex. 2. Petitioner's pain and reduced ROM were limited to the shoulder in which the vaccine was administered. Exs. 2 at 31; 5 at 106; 12 at 2.

E. Severity Requirement

The record supports the conclusion that the residual effects of Petitioner's condition continued for more than six months. Petitioner sought care for his shoulder condition soon after vaccination. At the second visit concerning shoulder pain, his condition appears to have been less pressing, and it appears that little or no evaluation or treatment was done.

Thereafter, Petitioner did not seek care again until over seven months later – a sizable gap that bridges the six-month severity “anniversary.” But when he did return to treatment, the records indicate, he reported that his condition had continued during this gap in time. There is no indication that his condition had fully resolved – and although the gap does suggest a less-severe injury, it is not *per se* evidence that his pain had lapsed entirely. Petitioner has also provided a reasonable explanation for the gap in care – a lack of medical insurance, which likely would have meant higher expenses for care had he addressed the problem during the period in which he was uninsured.

Altogether, the circumstances of this case suggest that Petitioner suffered a shoulder injury that was initially fairly intense, but improved somewhat in a short time. Perhaps due to a combination of the improvement in his condition and his loss of medical insurance coverage, he stopped seeking formal treatment for a time. However, his condition did not completely go away. When he returned to treatment, he reported a nine-month history of shoulder pain, and continued to have reduced ROM and positive impingement signs in his left shoulder, along with continued difficulty sleeping and driving. This is sufficient to meet the statutory threshold. See *Law v. Sec'y of Health & Human*

Servs., No. 21-0699V, 2023 WL 2641502 (Fed. Cl. Spec. Mstr. Feb. 23, 2023) (finding severity requirement met where the petitioner sought care for under three months, followed by a nearly five months treatment gap before returning to care). While the lengthy treatment gap does not render Petitioner's claim unmeritorious, it does bear on damages, and Petitioner should factor this in when preparing a revised demand.

F. Other Requirements for Entitlement

The record contains preponderant evidence that other requirements for entitlement are satisfied as well. Petitioner received a covered vaccine in the United States. Ex. 1 at 2. He averred that he has not previously collected an award or settlement of a civil action for damages for his vaccine-related injury. Ex. 9.

Conclusion

Based on my review of the record as a whole, I find that it is more likely than not that the residual effects of Petitioner's condition continued for at least six months. I find that all other SIRVA Table and QAI requirements are met, as are other requirements for entitlement. Therefore, Petitioner's motion for a ruling on the record that he is entitled to compensation is **GRANTED**.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master